



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2006-P-0136 (formerly Docket No. 2006P-0496) and Docket No. FDA-2007-P-0353 (formerly Docket No. 2007P-0034)]

Determination That AZO GANTANOL (Phenazopyridine Hydrochloride, Sulfamethoxazole) Tablet, 100 Milligrams/500 Milligrams, and AZO GANTRISIN (Phenazopyridine Hydrochloride, Sulfisoxazole) Tablet, 50 Milligrams/500 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that AZO GANTANOL (phenazopyridine hydrochloride (HCl) and sulfamethoxazole) Tablet, 100 milligrams (mg)/500 mg, and AZO GANTRISIN (phenazopyridine HCl and sulfisoxazole) Tablet, 50 mg/500 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for phenazopyridine HCl and sulfamethoxazole tablet, 100 mg/500 mg, and phenazopyridine HCl and sulfisoxazole tablet, 50 mg/500 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: David Joy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6254, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which

authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to FDA's approval of an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

AZO GANTANOL is the subject of NDA 013294, held by Roche and approved on April 8, 1965. AZO GANTRISIN is the subject of NDA 019358, held by Roche and initially approved on August 31, 1990. Under the Drug Efficacy Study Implementation (DESI), FDA concluded that a fixed combination drug product containing 500 mg of sulfamethoxazole and 100 mg of

phenazopyridine HCl, and certain other sulfonamide/phenazopyridine combinations, are effective for indications described in a Federal Register notice published on July 29, 1983 (DESI 12056, 48 FR 34516). Consistent with that determination, both AZO GANTANOL and AZO GANTRISIN are indicated for the initial treatment of uncomplicated urinary tract infections caused by susceptible strains of Escherichia coli, Klebsiella species, Enterobacter species, Proteus mirabilis, Proteus vulgaris, and Staphylococcus aureus when relief of symptoms of pain, burning, or urgency is needed during the first 2 days of therapy.

In a letter dated May 29, 1998, Roche requested that FDA withdraw approval of NDA 013294 for AZO GANTANOL (phenazopyridine HCl and sulfamethoxazole) Tablet, 100 mg/500 mg. In the Federal Register of September 25, 1998 (63 FR 51359), FDA announced that it was withdrawing approval of NDA 013294 effective September 25, 1998.

In a letter dated March 23, 1998, Roche requested that FDA withdraw approval of NDA 019358 for AZO GANTRISIN (phenazopyridine HCl and sulfisoxazole) Tablet, 50 mg/500 mg. In the Federal Register of May 12, 1998 (63 FR 26191), FDA announced that it was withdrawing approval of NDA 019358 effective June 11, 1998.

Vintage Pharmaceuticals, LLC, submitted a citizen petition dated December 1, 2006 (Docket No. FDA-2006-P-0136), under 21 CFR 10.30, requesting that FDA determine whether AZO GANTANOL and AZO GANTRISIN were withdrawn from sale for reasons of safety or effectiveness. JRRapoza Associates, Inc., submitted a citizen petition dated January 17, 2007 (Docket No. FDA-2007-P-0353), under 21 CFR 10.30, also requesting that FDA determine whether AZO GANTANOL and AZO GANTRISIN were withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and, under § 314.161, has determined that AZO GANTANOL (phenazopyridine HCl and sulfamethoxazole) Tablet, 100 mg/500 mg, and AZO GANTRISIN (phenazopyridine HCl and sulfisoxazole) Tablet, 50 mg/500 mg, were not withdrawn from sale for reasons of safety or effectiveness. We have also independently evaluated relevant literature and have found no information that would indicate that these products were withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list AZO GANTANOL (phenazopyridine HCl and sulfamethoxazole) Tablet, 100 mg/500 mg, and AZO GANTRISIN (phenazopyridine HCl and sulfisoxazole) Tablet, 50 mg/500 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other things, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to either AZO GANTANOL (phenazopyridine HCl and sulfamethoxazole) Tablet, 100 mg/500 mg, or AZO GANTRISIN (phenazopyridine HCl and sulfisoxazole) Tablet, 50 mg/500 mg, may be approved by the Agency if all other legal and regulatory requirements for the approval of ANDAs are met. If FDA determines that the labeling for either drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: June 6, 2014.

Leslie Kux,

Assistant Commissioner for Policy.